



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION OF)
Moriarty, R.M.; Penmasta, R.;)
Guo, L.; Rao, M.S.;)
and Mehta, R.G.)
SIL SERIAL NO.: 09/008,957)
FILED: Jan. 20, 1998)
TITLE: 1 α -HYDROXYVITAMIN D₅,)
ITS SYNTHESIS AND USE)
IN CANCER PREVENTION)
AND THERAPY)
Group No. 1616
Examiner: Badio

DECLARATION UNDER 37 CFR § 1.132

I, Rajendra G. Mehta, declare as follows:

1. I am a citizen of the United States residing at 11721 Springbrook Ct., Orland Park, Illinois 60462.
2. I am a graduate of the University of Nebraska, having received a Ph.D. in 1974. I have been conducting cancer research for the past 25 years. My principal area of interest is identifying and evaluating novel cancer preventive and therapeutic agents in experimental models and understanding their mechanism of action.
3. I am currently a professor in the departments of surgical oncology and pharmacology in the College of Medicine at the University of Illinois at Chicago. I have published 185 papers and abstracts in peer reviewed journals and proceedings.
4. Recently I conducted tests to study the effect of 1 α -hydroxyvitamin D₅ on body weight and serum calcium level in rats with the following results. Administration of 1 α -hydroxyvitamin D₅ to rats at concentrations of 50 μ g/kg diet and 25 μ g/kg diet for

114 days did not significantly reduce body weight gain. The average calcium level from five blood samples in control rats was 9.07 mg/dL, compared to 8.1 mg/dL in rats given 25 μ g of Vitamin D5/kg diet and 11.85 mg/dL in rats given 50 μ g of Vitamin D5/kg diet. The serum calcium level in the high dose group (11.85 mg/dL) is considered safe since there was no liver or kidney toxicity found and there was no reduction in body weight gain. The hypocalcemia in the low dose group was quite unexpected, and suggests that the proper dose of 1 α -hydroxyvitamin D₅ might not affect serum calcium levels at all. These data show that 1 α -hydroxyvitamin D₅ continues to be a promising candidate for cancer prevention and therapy.

5. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent that may issue from the above-identified U.S. patent application.


Rajendra G. Mehta, Ph.D.

7/2/99
Date